EXHIBIT 18

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

Memorandum

Date MAY 8 1998

From June Gibbs Brown
Inspector General

Subject Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs (A-06-97-00052)

To Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration

Attached is our final report of the Department of Health and Human Services, Office of Inspector General entitled, "Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs." Enactment of a legislative change requiring that rebates be based on average wholesale price (AWP) would have resulted in about $1.15 billion in added Medicaid rebates for the Calendar Years 1994 through 1996 for only the top 100 drugs for each calendar year used in our analysis. Requiring manufacturers to pay Medicaid drug rebates based on AWP would:

- Eliminate inconsistencies in the present methods used by drug manufacturers to calculate average manufacturers price (AMP);
- Establish a much needed connection between the calculation of Medicaid drug rebates and the calculation of Medicaid's reimbursement for drugs at the pharmacy level; and
- Reduce the burden of administering the Medicaid drug rebate program at the Federal, State, and manufacturer levels.

We recommended that the Health Care Financing Administration (HCFA) develop and submit a legislative proposal to the Congress that would require drug manufacturers participating in the Medicaid outpatient prescription drug program to pay Medicaid drug rebates based on AWP.

In responding to our draft report, HCFA disagreed with our recommendation for development and submission of a legislative proposal to Congress on this issue. The HCFA does not believe that such legislation is feasible at this time. A statement was made by HCFA, however, that changing from AMP to AWP would reduce the administrative burden involved in the AMP calculations. However, the response stated that the calculation of AWP itself needs to be examined, and HCFA is planning a comprehensive study of AWP.

We appreciate HCFA's position of not wanting to seek a legislative proposal at this time but continue to believe that such a legislative change would significantly improve the Medicaid

drug rebate program. Over the last several years, our staffs have worked well together on Medicaid drug rebate issues. We look forward to that continued outstanding relationship and offer our assistance to HCFA as you contemplate changes to the Medicaid drug program.

We would appreciate your views and the status of any further action taken or contemplated on our recommendations within the next 60 days. If you have any questions, please contact me or have your staff contact George M. Reeb, Assistant Inspector General for Health Care Financing Audits, at (410) 786-7104.

To facilitate identification, please refer to Common Identification Number A-06-97-00052 in all correspondence relating to this report.

Attachment

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

NEED TO ESTABLISH CONNECTION BETWEEN THE CALCULATION OF MEDICAID DRUG REBATES AND REIMBURSEMENT FOR MEDICAID DRUGS

JUNE GIBBS BROWN
Inspector General

MAY 1998
A-06-97-00052

DEPARTMENT OF HEALTH & HUMAN SERVICES Office of Inspector General

Memorandum

Date MAY 8 1998

From June Gibbs Brown
Inspector General

Subject Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs (A-06-97-00052)

To Nancy-Ann Min DeParle
Administrator
Health Care Financing Administration

This final report provides you with our analysis of enhanced Medicaid revenues possible through use of the average wholesale price (AWP) in the calculation of Medicaid drug rebates. Since the inception of the Medicaid prescription drug rebate program which was created by the passage of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), the Office of Inspector General (OIG) has reviewed major aspects of the rebate program and recommended program improvements. The Health Care Financing Administration (HCFA) has been supportive of our efforts and has implemented many of our recommendations.

An Anomaly: Medicaid drug purchases are made using average wholesale prices while drug rebates are made using average manufacturers prices

However, we believe that HCFA has an opportunity to address an issue which impacts the very core of the program--the disparity between how Medicaid drug rebates are based and calculated, and how the Medicaid program reimburses pharmacies for prescription drug purchases. We believe that the current program of basing rebates on a manufacturer calculated average manufacturers' price (AMP) should be changed to calculating rebates based on AWP.

Enactment of a legislative change requiring that rebates be based on AWPs would have resulted in about $1.15 billion in added Medicaid rebates for the Calendar Years (CY) 1994 through 1996 for only the 100 drugs used in our analysis.[1] Requiring manufacturers to pay Medicaid drug rebates based on AWP would:

- Eliminate inconsistencies in the present methods used by drug manufacturers to calculate AMP;
- Establish a much needed connection between the calculation of Medicaid drug rebates and the calculation of Medicaid's reimbursement for drugs at the pharmacy level; and

[1]We studied the financial effects for the 100 brand name drugs comprising the highest total of Medicaid reimbursements in each of the CYs.

- Reduce the burden of administering the Medicaid drug rebate program at the Federal, State, and manufacturer levels.

We recommended that HCFA develop and submit a legislative proposal to the Congress that would require drug manufacturers participating in the Medicaid outpatient prescription drug program to pay Medicaid drug rebates based on AWP. We recognize that the opportunity exists that manufacturers could manipulate such a new system but believe that the normal competitive pressures on drug prices in the marketplace would discourage manufacturers from inordinately raising drug prices. However, we are also recommending that if our recommended change is enacted, HCFA should establish safeguards as part of the new rebate process to discourage manufacturers from inordinately raising drug prices to pay for the cost of the additional rebates and at the same time raising AWP to cover the amount of the increased cost to the pharmacies. One such safeguard would be for HCFA to complete an analysis of the historic AWP increases and seek authority to establish appropriate indexing methodology for use when AWP increases would exceed inflation.

We believe strongly that the Medicaid reimbursement and rebate methodologies for pharmaceutical transactions needs to be based on the same type of information. Therefore, if HCFA is not in agreement with supporting our recommended legislative proposal, then we are recommending that HCFA study alternative methods of calculating Medicaid drug rebates which would address our concerns with the current program.

In responding to our draft report, HCFA disagreed with our recommendations because they did not believe such legislation was feasible at this time. However, HCFA did agree that changing from AMP to AWP would reduce the administrative burden involved in the AMP calculations. And, HCFA believes the calculation of AWP itself needs to be examined. The full text of the Administrator's comments is included as Appendix 2 to this report.

BACKGROUND

The OBRA 90 authorized States to collect rebates from drug manufacturers for drug purchases made under the Medicaid program. In order for a manufacturer's drugs to be eligible for reimbursement under Medicaid, the manufacturer was required by OBRA 90 to enter into a rebate agreement with HCFA and pay quarterly rebates to the States. The rebate is based on the AMP paid by wholesalers for drugs distributed to the retail pharmacy class of trade. Rebates are calculated by manufacturers separately for brand name drugs and generic drugs. For brand name drugs, the rebate amount is determined by taking the greater of either AMP minus the manufacturer's best price (lowest price) or a specified percentage, currently 15.1 percent of AMP. The rebate for generic drugs is calculated as 11 percent of AMP. There is an additional rebate amount for brand name drugs equal to the amount that AMP increases over and above the consumer price index. The AMP was indexed to the Consumer Price Index-Urban as of September 1990.

Contrary to how the above rebates are calculated, most States reimburse pharmacies for Medicaid prescription drugs based on the AWP of the drug. The AWP is the price assigned to the drug by its manufacturer and is listed in either the **Red Book**, **Medispan**, or the **Blue**

Book—publications nationally recognized for drug product and pricing information. Reimbursement is predominantly calculated as about 10 percent discount off the AWP.

Objective, Scope, and Methodology

The objective of this report was to provide HCFA with information on the impact of using AWP instead of AMP in the Medicaid drug rebate calculation. We developed this information by consolidating the results of our work performed at drug manufacturers and results from other audits of drug rebate issues. We also identified related benefits which could result from this proposal and calculated any additional rebates that could be realized by introducing a legislative change to modify the present drug rebate formula.

Our calculations of the increased rebates that could be realized by using AWP in place of AMP were for only the 100 brand name drugs which comprised the highest total amount of Medicaid reimbursements in each of the CYs 1994, 1995, and 1996. The estimate of rebate amounts using AWP was calculated by substituting AWP for AMP in the rebate formula and did not include the additional rebate calculations related to indexing. For each quarter's rebate calculation, we used the AWP that was in effect as of the end of that quarter. For the estimate of actual rebate amounts, we used the unit rebate amounts recorded in the HCFA Data Center, which included the additional rebate from indexing. Therefore, our estimated increase in the use of AWP is understated because we did not apply an indexing amount to our AWP based rebate calculation.

RESULTS OF REVIEW

Significant improvements to the Medicaid outpatient prescription drug rebate program are possible by having legislation enacted which would require participating drug manufacturers to pay Medicaid drug rebates based on AWP rather than AMP. Such a change would:

- Eliminate inconsistencies in the present methods used by drug manufacturers to calculate AMP;
- Establish a much needed connection between the calculation of Medicaid drug rebates and the calculation of Medicaid reimbursements for drugs at the pharmacy level; and
- Reduce the burden of administering the Medicaid drug rebate program at the Federal, State, and manufacturer levels.

If this change is enacted, we believe that HCFA should establish safeguards as part of the new rebate process to discourage manufacturers from raising the prices they charge pharmacies to pay for the additional cost of the rebates while at the same time raising AWP to offset these price increases to the pharmacies. Such manipulation could result in an overall increase in the total cost of the Medicaid program. One such safeguard would be for HCFA to complete an analysis of the historic AWP increases and seek authority to establish an appropriate indexing methodology for use when AWP increases would exceed inflation. If HCFA is not in agreement with such a legislative proposal, then we believe that HCFA

should study alternative methods of calculating Medicaid drug rebates which would address our concerns with the current program. An alternative such as the calculation of the rebate based on the use of a flat percentage of drug manufacturers' sales would greatly simplify the program and address most of our concerns with the current program but also only if this methodology also included an excessive inflationary index calculation.

Inconsistent Methods Used by Drug Manufacturers to Calculate AMP

The AMPs submitted by drug manufacturers to HCFA provide the foundation upon which the entire Medicaid drug rebate program is based. However, we found that manufacturers have used inconsistent methods to calculate AMP because these manufacturers have interpreted the definition of AMP differently. In our first review of drug manufacturers involving four companies, we reported in 1992 that these companies used three different methods to calculate AMP because they lacked specific guidance on how to calculate AMP [Medicaid Drug Rebates: The Health Care Financing Administration Needs to Provide Additional Guidance to Drug Manufacturers to Better Implement the Program (A-06-91-00092)]. One of the manufacturers based the calculations on gross sales to its wholesalers, two of the manufacturers based the calculations on net sales to their wholesalers and another manufacturer specifically identified sales at the retail level for its calculations. As a result, we were unable to express an opinion on the accuracy of the AMP calculations at these manufacturers. The HCFA responded to our report and its recommendations by stating their intention to clarify the description of AMP in a future regulation. However, with input from the OIG, HCFA is continuing to revise final regulations for the drug rebate program. These revisions include changes to the definition of adequate documentation, retail class of trade, and AMP calculations.

In 1994, we reviewed another drug manufacturer's AMP calculations and we were again unable to express an opinion on the accuracy of the AMP calculations. This manufacturer used a methodology to compute AMP which it could not support. In that report, we also cautioned HCFA that manufacturers may submit revised AMP calculations and that such retroactive calculations could pose potentially significant liabilities to both the States and the Federal Government.

Subsequently, another drug manufacturer claimed that it had incorrectly calculated AMP and requested a multi-million dollar retroactive adjustment to its rebate payments. The HCFA approved the adjustment (subject to OIG audit) and allowed the manufacturer to offset the adjustment against current rebate payments to the States. The HCFA also allowed the manufacturer to use the revised methodology for its current and future AMP calculations, but requested that the OIG audit the manufacturer's calculations. We issued another disclaimer of opinion on the AMP calculations because of problems with the definition of AMP at this manufacturer.

We believe that as long as drug rebates are based on AMP as currently defined, HCFA will have continuing problems with manufacturers interpreting AMP differently due to differences in business philosophies, accounting systems, and market structure. We believe that as manufacturers find that AMP can be interpreted more to their benefit, additional requests for retroactive adjustments as well as changes in current and future calculations will

be forthcoming. This could significantly impact upon liabilities of the States and the Federal Government as well as impacting future Medicaid drug rebate revenue.

Connection Between How Rebates Are Paid and How Drugs Are Reimbursed

Under the present Medicaid prescription drug program, there is no direct financial connection between the calculation of Medicaid drug rebates and the calculation of Medicaid reimbursements to pharmacies for prescription drugs. As discussed above, drug manufacturers pay rebates by using AMP in the rebate formula. However, most States reimburse pharmacies based upon AWP less a discount of about 10 percent.

Because AWP is usually used as a basis for reimbursement at the pharmacy level, manufacturers can use it as a marketing tool to gain market share. For example, by increasing AWP, manufacturers can give pharmacies more Medicaid reimbursement without having to make additional rebate payments. The drug industry currently treats AWP as a published list price rather than a true wholesale price.

Recently, we met with representatives from eight State Medicaid pharmacy programs to discuss our proposal to directly relate the calculation of rebates with the calculation of reimbursements. These officials were very supportive of our proposal and believed that such a change would make AWP a more meaningful and accurate number.

Reducing the Burden of Administering the Rebate Program

The creation of the new Medicaid rebate program with the passage of OBRA 90 placed a significant administrative burden on HCFA, the States, and the drug manufacturers. Requiring drug manufacturers to pay rebates based on AWP would reduce the administrative burden at HCFA and manufacturers. The HCFA would no longer have to collect AMP data from manufacturers but could use published AWP data. Drug manufacturers would no longer have to calculate AMP for a multitude of drug products by capturing data through accounting systems which were not originally designed for this purpose. Although drug manufacturers now have these systems in place, we believe that manufacturers would welcome being relieved from this burden.

By changing from AMP to AWP, manufacturers could easily manipulate, through changes to the published AWPs, how much rebates they pay. However, reductions in rebates due to reductions in the AWPs set by manufacturers would also result in a corresponding reduction in Medicaid pharmacy reimbursements. Another possibility would be unwarranted or unsupported increases in the AWP values. Manipulation of AWPs by raising them greater than the rise in rebate values would unfairly enrich manufacturers if manufacturers raised the prices they charge pharmacies. Therefore, including an indexing methodology in a revamped rebate calculation methodology that uses AWP as the base would be needed to discourage manufacturers from any pricing manipulations.

Calculation of Potential Increases in Rebates

We calculated that using AWP in place of AMP could have resulted in $1.15 billion more in drug rebates for 100 brand name drugs which had the greatest amount of Medicaid reimbursements in each CY of 1994 through 1996. The estimate of rebate amounts using AWP was calculated by substituting AWP for AMP in the rebate formula and did not include the additional rebate calculations related to indexing. Therefore, our savings calculation is understated.

For each quarter's rebate calculation, we used the AWP that was in effect as of the end of that quarter. For the estimate of actual rebate amounts, we used the unit rebate amounts recorded in the HCFA Data Center, which included the additional rebate from indexing. Although significant savings could be achieved upon passage of proposed legislative changes, HCFA could include a phase-in period to alleviate concerns regarding the adverse impact that may occur if a sudden change were made in the rebate program.

The following chart depicts the results of our calculations:

Calendar Year	Actual Rebates (millions)	Rebates Based on AWP (millions)	Increase in Rebates (millions)
1994	$685	$1,038	$353
1995	$726	$1,089	$363
1996	$735	$1,167	$432
Totals	$2,146	$3,294	$1,148

We recognize that there is the potential for manufacturers to manipulate the system if the basis for rebate calculations is changed from AMP to AWP. For example, manufacturers could significantly raise the prices they charge to pharmacies for drugs to cover the additional cost of rebates based upon AWP. The manufacturers could then offset this added cost to the pharmacies with even larger increases in the published AWP. This would result in a higher overall cost to the Medicaid program.

We believe that the normal competitive pressures on drug prices in the marketplace would discourage manufacturers from inordinately raising drug prices under such a scenario. However, we believe that HCFA should implement appropriate safeguards to preclude such manipulation if legislation is enacted to make AWP the basis for rebates. These safeguards could involve HCFA studying AWP increases and taking action to limit reimbursement when AWP increases exceed historic increases through the establishment of an appropriate indexing methodology. For the top 100 brand name drugs, the increases in AWP were 4.04 percent for the period January 1, 1994 to December 31, 1994, 3.71 percent for the period January 1, 1995 to December 31, 1995, and 3.91 percent for the period January 1, 1996 to December 31, 1996.

Other Alternatives

If HCFA is unwilling to support a legislative change, then we believe that HCFA should study other viable alternatives to the current program which would address the current problems with the use of AMP. For example, a greatly simplified rebate program which calculates rebates as a percentage of a manufacturer's gross sales would address definitional and documentation problems and administrative burdens associated with using AMP.

CONCLUSIONS AND RECOMMENDATIONS

While basing rebates on AMP is mandated by current legislation, we believe that a legislative change to have manufacturers pay rebates based on AWP would be a major improvement to the Medicaid drug rebate program. Such a change would resolve manufacturers' definitional problems with AMP, preclude the likelihood of future retroactive requests for rebate refunds and provide relief on the burden for administering the program. Significant cost savings could also be achieved. We also recognize that safeguards may need to be established to discourage manufacturers from inordinately raising prices to offset the cost of the additional rebates. Lastly, we recognize that there may be other alternatives that need further study. Therefore, we recommend that HCFA:

- Develop and submit a legislative proposal to the Congress which would require participating drug manufacturers to pay rebates based upon AWP. We are available to work with HCFA officials to develop specific language for the recommended proposal.

- If such a proposal is enacted, establish safeguards to ensure that manufacturers do not raise AWP to pay for the cost of the additional rebate collections by in turn raising the prices paid by pharmacies. The HCFA could study historic AWP increases and take action through the establishment of an appropriate indexing methodology if AWP increases exceed inflation.

- Study other viable alternatives to the current program of using AMP to calculate the Medicaid rebates. Alternatives such as the establishment of a flat percentage of manufacturers gross sales to calculate rebates could greatly simplify the program.

HCFA COMMENTS

In responding to our draft report, HCFA disagreed with our recommendation for development and submission of a legislative proposal to Congress on the issue. The HCFA does not believe that such legislation is feasible at this time. A statement was made by HCFA, however, that changing from AMP to AWP would reduce the administrative burden involved in the AMP calculations. However, the response stated that the calculation of AWP itself needs to be examined, and HCFA is planning a comprehensive study of AWP.

We appreciate HCFA's position of not wanting to seek a legislative proposal at this time but continue to believe that such a legislative change would significantly improve the Medicaid drug rebate program. Over the last several years, our staffs have worked together on

Medicaid drug rebate issues. We look forward to that continued outstanding relationship and offer our assistance to HCFA as you contemplate changes to the Medicaid drug program.

Summary of Increases in Rebates from Basing Medicaid Drug Rebates on AWP

Drugs*	1994	1995	1996
1	$20,814,635.87	$19,419,447.19	$32,647,280.39
2	19,470,833.54	15,419,174.04	18,659,304.37
3	7,079,730.35	8,181,797.05	9,385,035.79
4	11,527,706.58	13,082,939.33	18,736,901.30
5	14,188,361.72	11,132,272.23	7,904,576.90
6	4,363,495.22	5,510,331.97	13,288,589.15
7	7,712,113.20	3,235,907.78	10,478,074.06
8	3,257,290.53	7,665,484.74	8,553,629.53
9	3,980,647.43	8,415,529.18	7,147,904.56
10	7,890,947.69	2,257,061.94	10,200,269.01
11	2,810,101.59	3,963,039.62	5,310,228.05
12	8,761,991.43	8,683,883.96	12,093.94
13	2,155,376.87	8,649,940.66	3,694,594.53
14	6,132,031.75	9,218,922.21	1,111,026.74
15	2,608,809.69	2,533,819.66	9,942,726.41
16	7,799,141.11	3,652,312.31	8,493,071.38
17	4,127,912.81	5,996,057.95	4,956,558.31
18	5,990,904.95	5,784,488.73	8,938,452.83
19	6,109,911.89	8,676,679.48	7,967,156.38
20	1,156,933.65	2,667,568.86	3,488,888.53
21	871,773.19	294,563.59	6,169,318.08
22	2,587,817.35	594,708.52	5,920,636.95
23	5,934,997.46	5,699,844.22	7,656,180.60
24	(2,714,778.07)	6,176,352.72	781,819.30
25	4,787,256.51	6,724,980.40	3,979,057.09
26	3,664,343.76	5,314,701.07	(378,649.79)
27	8,124,204.93	4,855,555.28	6,035,359.83
28	5,022,655.45	818,348.65	4,525,191.11
29	748,125.94	4,354,411.27	2,587,553.92
30	2,573,459.87	2,738,361.99	6,003,361.41
31	3,045,546.46	5,886,489.76	1,032,560.46
32	5,361,187.55	(3,775,723.48)	6,872,673.37
33	5,199,997.37	5,812,747.94	6,315,208.91
34	3,358,051.32	5,413,338.77	5,582,613.76
35	2,338,363.89	515,026.32	5,499,952.66
36	4,644,144.66	5,527,590.80	1,948,631.25
37	(1,745,834.47)	2,584,775.90	(4,100,614.44)
38	714,324.66	5,220,881.58	4,173,189.90
39	2,179,865.65	2,302,310.69	1,107,916.89
40	3,865,589.61	2,302,878.84	5,516,037.36
41	4,797,375.19	8,606,420.76	6,083,315.82

Summary of Increases in Rebates from Basing Medicaid Drug Rebates on AWP

Drugs*	1994	1995	1996
42	$4,327,565.29	$4,603,779.42	$2,606,060.63
43	2,147,258.84	(2,212,521.99)	4,280,576.55
44	3,539,643.42	4,055,078.49	3,002,570.51
45	4,507,067.92	(3,036,425.03)	(3,403,099.92)
46	3,263,240.78	6,086,840.03	3,615,586.16
47	6,036,152.57	2,915,417.22	(3,410,793.16)
48	1,506,711.09	2,287,283.67	8,361,659.41
49	2,062,237.58	2,024,531.91	2,724,437.39
50	(1,990,857.28)	1,585,704.17	5,151,002.91
51	11,799,114.32	2,308,609.91	4,857,157.56
52	1,950,395.54	4,560,678.22	3,707,669.09
53	1,157,707.31	3,368,704.11	5,217,609.64
54	3,289,421.36	1,122,929.75	4,511,092.05
55	981,388.28	3,898,876.10	2,921,132.87
56	1,159,718.05	1,142,813.12	2,483,790.54
57	2,178,707.39	3,017,728.38	3,051,875.82
58	4,242,308.60	2,222,057.33	4,712,723.81
59	2,804,611.06	10,769,548.93	3,573,468.64
60	1,541,888.09	2,031,624.94	4,341,222.52
61	3,208,855.58	3,686,358.95	4,564,079.60
62	3,689,427.23	3,904,601.87	3,363,671.81
63	1,319,367.69	1,724,497.06	3,900,717.51
64	2,595,961.23	2,556,148.32	2,826,120.77
65	3,130,260.76	611,001.35	3,276,100.70
66	1,789,009.52	3,324,130.78	1,105,618.80
67	2,602,436.67	3,747,927.32	3,025,129.80
68	1,248,499.77	2,694,068.24	3,470,780.23
69	1,360,049.60	1,439,813.22	4,431,607.85
70	4,642,037.38	2,460,769.07	1,215,971.77
71	2,448,505.29	1,615,017.85	3,419,302.28
72	822,758.90	1,387,916.54	647,920.86
73	2,262,192.07	2,388,826.88	2,367,857.90
74	792,409.01	1,213,809.77	1,026,315.83
75	2,861,027.55	3,193,552.05	1,635,254.62
76	4,861,186.41	2,896,174.54	13,186,929.69
77	3,276,246.50	2,661,067.79	658,404.85
78	6,271,455.43	3,251,271.30	7,300,295.66
79	2,780,890.23	3,171,767.40	2,742,464.48
80	(681,069.91)	2,578,987.65	1,541,450.70
81	884,742.47	849,595.72	729,384.43
82	1,144,404.23	970,198.20	3,576,216.40

Summary of Increases in Rebates from Basing Medicaid Drug Rebates on AWP

Drugs*	1994	1995	1996
83	$2,033,553.76	$861,562.52	$2,218,790.61
84	692,675.05	1,103,466.06	1,928,308.79
85	(986,743.49)	1,082,824.26	2,814,707.56
86	2,736,853.87	815,526.91	393,756.83
87	756,682.83	1,872,896.14	2,166,304.01
88	1,258,038.57	1,039,002.82	2,285,342.09
89	1,022,331.63	(1,401,409.31)	1,437,896.25
90	2,887,375.68	1,004,608.41	1,173,801.28
91	2,067,522.36	4,859,233.90	1,554,716.60
92	1,114,847.40	800,854.96	1,721,386.63
93	839,580.13	2,728,437.43	(765,102.78)
94	4,299,171.16	2,316,663.90	(2,203,738.05)
95	(551,930.64)	3,331,152.73	883,624.55
96	2,750,992.70	1,116,383.96	1,449,809.30
97	1,926,143.37	1,900,768.37	1,163,073.42
98	1,093,922.71	603,321.76	1,098,086.29
99	3,194,615.44	1,668,654.67	4,552,957.51
100	2,926,224.82	277,900.34	1,513,729.41
	$353,174,137.32	$363,177,834.86	$431,932,466.46

* Top 100 brand name drugs for each calendar year.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

The Administrator
Washington, D.C. 20201

DATE: APR 6 1998

IG ✓
EAIG
SAIG
PDIG ✓
DIG-AS ✓
DIG-EC
DIG-EI
DIG-OI
DIG-MP
AIG-LC
OGC/IG ✓
ExecSec
Date Sent 4-9

TO: June Gibbs Brown
Inspector General

FROM: for Nancy-Ann Min DeParle
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: "Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs" (A-06-97-00052)

We reviewed this draft report, and greatly appreciate OIG's efforts in evaluating the Medicaid drug rebate program. However, we do not agree with the report's specific recommendation that the Health Care Financing Administration (HCFA) propose legislation to require that Medicaid rebates be based on the average wholesale price (AWP).

We do not believe such legislation would be feasible at this time. Manufacturers already appear to be paying significantly more in rebates than was anticipated when the rebate program was initiated. This would make passage of any such legislation highly unlikely in the immediate future.

Based on recommendations in other OIG reports, we have provided manufacturers with clarification on the proper calculation of the average manufacturer price (AMP). Recalculations by manufacturers based on HCFA's guidance have resulted in retroactive adjustments.

We do agree that changing from AMP to AWP would reduce the administrative burden involved in the AMP recalculations. However, calculation of AWP itself needs to be examined. We are planning a thoughtful, comprehensive study of issues such as how AWP is defined; how to safeguard against manipulation of AWPs to maximize reimbursement or minimize rebates; how to verify the accuracy of AWPs; the need for an indexing factor; and differences in AWPs for brand name versus generic drugs.

We look forward to working with OIG in examining and refining the current AWP process so that it can benefit the Medicaid drug program.